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Original research article

Influence of two conservative treatment methods on foot health status in men with chronic calcaneal spur: A randomized controlled study

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ABSTRACT

Objective: This study compared the effectiveness of extracorporeal shockwave therapy (ESWT) with ultrasound therapy (US – control group) in preventing social limitations and the improvement of foot health status (FHS) in men with a chronic calcaneal spur (CS).
Material and methods: Forty men were randomly allocated and then received ESWT or US therapy. Two people from the US group ignored the call for study 3 months later, so they were excluded. Therefore, 38 men were analyzed. The ESWT group received 5 treatments once a week, and sessions took place at weekly intervals. Meanwhile, the US group received 10 treatments, 3 times per week. The FHS was assessed using a foot health status questionnaire (FHSQ). The scores were recorded and compared within the groups and between the groups pre treatment, immediately post treatment, and 3 months post treatment.
Results: We found a significant improvement of FHS and reduction of social limitations immediately post treatment (up to 3 months post treatment in patients with chronic CS).
Conclusion: The results of this study provide evidence that patients with CS can obtain greater significant health benefits of the foot care when treated by ESWT, rather than by US.

Introduction

CS occurs when calcium deposits build up on the underside of the heel bone, a process that usually occurs over a period of many months. CS often causes foot muscle strain, inflammation of the PF, repeated tearing of the membrane that covers the heel bone, and pain. CS decreases physical activity, social capacity, deterioration of quality of life, and becomes the cause of frequent absence from work due to sickness. Chronic CS is a disease commonly appearing in adults, and it is also a serious social problem. Australian research points out that it appears in 3.6% of their population (the study included 3206 people), and American

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research says that it concerns 7% of their population over 65 years old [1, 2]. There is no such research in Poland.

Risk factors for CS include: excess weight and obesity, flat feet, long periods of standing at work, jogging (especially on hard surfaces), poorly fitted or badly worn shoes (especially those lacking appropriate arch support), and walking gait abnormalities, which place excessive stress on the heel bone, ligaments, and nerves near the heel [3–11].

The conservative treatment of CS is mainly analgesic. The previous studies have shown, that ESWT and US effectively reduce pain [12–21], but there are no comparative studies of the FHS and social limitation prevention following ESWT and US treatments in patients with CS. Therefore, the aim of the study was to compare the influence of ESWT and US on improving the FHS and social limitation prevention in men with chronic CS post treatment and 3 months afterwards.

Materials and methods

From January 2013 until December 2014, the men with unilateral CS were examined. This study was performed in the Department of Physiotherapy, Jaworzno, and in the Spa and Rehabilitation, Busko-Zdroj, Poland. The exclusion criteria were local soft-tissue infection, malignant disease, pacemaker, epileptic disorders, rheumatoid arthritis, diabetes mellitus, neurological abnormalities, cardiovascular disease, lung or endocrine disease, skin ulcerations, previous surgical removal of the CS or previous conservative treatment of the CS 12 weeks before the beginning of the study, and history of local corticosteroid injection 12 weeks before the study. The inclusion criteria obtained men diagnosed with unilateral X-ray on the CS at the minimum age of 40, and who had pain under the calcaneal tuber persisting longer than 6 months (Table 1).

Table 1 – Baseline characteristics

Personal characteristics	ESWT group	US group
Sex (male)	20	18
Age (yr)	54.1 ± 6.2[a]	55.3 ± 5.4[a]
Height (m)	176.8 ± 5.7[a]	178.0 ± 5.7[a]
Mass (kg)	77.0 ± 6.8[a]	77.8 ± 5.8[a]
BMI (kg/m^2)	24.40 ± 0.99[a]	24.55 ± 0.92[a]
Obese men	0	0
Level of education (*n*):		
Primary school graduates	8	10
Secondary school graduates	6	5
University graduates	6	3
Occupation: physical worker/ white-collar worker (*n*)	14/6	15/3
Marital status – single/married (*n*):	5/15	4/14
Duration of symptoms (months)	8.5 ± 1.5[a]	8.0 ± 1.2[a]
Unilateral symptoms (left/right foot)	8/12	6/12
Location of pain (calcaneal tuber)	20	18

[a] Values are mean ± SD.

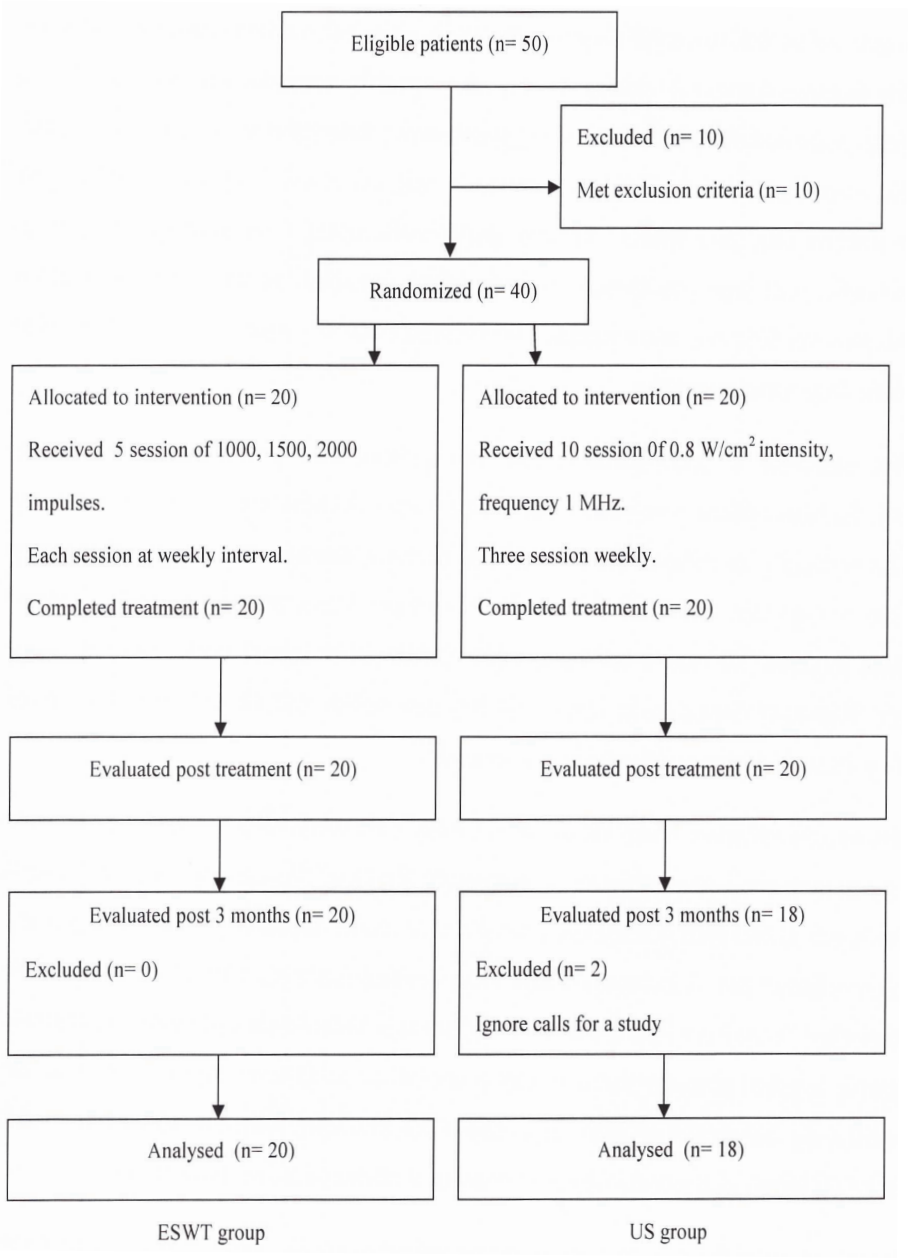
After the enrollment of 50 patients, 10 patients met the exclusion criteria (2 with rheumatoid arthritis, 4 who received previous conservative treatment 12 weeks before the beginning of the study, and 4 with diabetes mellitus). The remaining 40 participants were divided on a 1:1 ratio using a simple random number table into two treatment groups: ESWT and US (control group). Randomization was completed before the first treatment. The researchers responsible for analyzing the data were blinded to the type of treatment procedure. Before the experiment, all participants were informed that they receive treatment with ESWT or US.

We excluded 2 patients from the US group because they ignored the call for study 3 months after the treatment was over. Finally, a total of 38 individuals from 2 groups were statistically analyzed (Scheme 1). This study was designed with respect for the rules of conducting experimental studies with humans after approval by the Bioethical Committee at the Holy Cross College in Kielce – protocol number 1/13/15012013KB, and were similar to those set out in the Declaration of Helsinki. All participants signed consent forms and knowingly participated in the study.

The ESWT group received 1000, 1500, and 2000 pulses during the first, second, and third through fifth treatments respectively (pressure, 2.5 bar; frequency, 8 Hz; energy density, 0.4 mJ/mm^2). The patients received 5 ESWT treatments once per week, and each session was completed at a weekly interval. The treatments were performed using a Rosetta ESWT (CR Technology, Korea). Ultrasound gel was applied between the apparatus head and skin. The procedure was performed in the area with the most intense pain. Treatment was administered on the underside of the heel bone, in the area of the calcaneal tuber. The treatment time did not exceed 10 minutes. During treatments the patients did not receive any drugs.

Meanwhile, the US group received continuous ultrasound waves: intensity, 0.8 W/cm^2; 100% fill; carrier frequency, 1 MHz. The patients received a series of 10 treatments, 3 times per week. The treatments were performed using a US 13 EVO Cosmogamma (Emildue, Italy). The active engagement between the apparatus head and skin was ultrasound gel. The applicator head was applied to the calcaneal tuber at a right angle in order to maximize energy absorption by the tissue. Each treatment session did not exceed 10 minutes. During the treatment, the patients did not receive any drugs.

We measured the FHS pretreatment, immediately post treatment and 3 months post treatment by FHSQ, which comprises 3 sections. Section I has 13 questions that assess 4 health domains concerning feet: Foot Pain (FP), Foot Function (FF), Foot Wear (FW), and General Foot Health (GFH). Section II comprises 20 questions that assess patient's health in 4 domains: General Health (GH), Physical Function (PF), Social Capacity (SC) and Vitality (V). These are generic health measurements similar to those in the SF-36 questionnaire. Each question allows several answers and these are placed on a Likert-type ordinal scale (words or phrases corresponding to a numeric scale). The descriptors for these scales vary for each domain. The person completing the questionnaire has to choose only one response, whichever is thought



Scheme 1 – Study flow diagram

to be the most appropriate. Section III collects standard demographic data and variables like; socioeconomic status, co-morbidity, etc. FHSQ data analysis software© (Version 1.03) was used to convert the initial score for each domain to a score between 0 and 100 (worst to best condition).

Statistical analysis

SPSS Statistical Software version 20.0 (SPSS, Inc., Chicago, IL, USA) was used for the statistical analyses. The data are presented as the mean ± standard deviation (SD), mean difference (MD) and 95% confidence interval (95% CI). All of the variables presented normal distributions according to Shapiro-Wilk tests. Repeated-measure analyses of variance (ANOVA) were used to assess the variables differences of ESWT and US within the groups from the pretreatment time up to 3 months post treatment. When there were significant group-by-time interactions, the independent samples *t*-test was used to identify the specific differences within the groups at each assessment point. The level of significance was set at $p < 0.05$.

Results

In both groups the foot health status in Section I and Section II was similar at pretreatment time. We found a statistically significant improvement in the results of the

FHSQ from the pre treatment time up to 3 months post treatment in both groups in Section I and in Section II ($p < 0.05$), but in favor of the ESWT group (Table 2, Chart 1 and 2). The results of the independent sample t-test showed significant differences in Section I and Section II domains within the groups at post treatment time, which persisted for up to 3 months post treatment ($p < 0.05$) in favor of the ESWT group (Table 3, Chart 3 and 4).

Table 2 – Differences within groups in the following terms of research

Domain	ESWV group					US group				
	Pre treatment	Post treatment	Post 3 months	*F*	*p*	Pre treatment	Post treatment	Post 3 months	*F*	*p*
FP Mean (SD)	54.0 (5.0)	69.8 (8.9)	88.9 (5.0)	141.717	0.000[a]	52.7 (7.4)	57.6 (8.8)	60.7 (9.2)	4.443	0.016[a]
FF Mean (SD)	56.7 (7.1)	70.5 (6.3)	89.2 (7.3)	111.444	0.000[a]	54.7 (5.2)	59.0 (7.0)	63.0 (9.8)	5.927	0.005[a]
FW Mean (SD)	43.8 (3.5)	61.6 (4.5)	89.1 (3.3)	708.742	0.000[a]	43.5 (3.2)	47.6 (9.0)	51.9 (11.5)	4.762	0.012[a]
GFH Mean (SD)	45.2 (5.2)	63.7 (5.0)	86.8 (4.4)	365.102	0.000[a]	43.9 (4.8)	47.2 (5.8)	53.2 (12.3)	6.475	0.003[a]
GH Mean (SD)	43.6 (4.8)	64.6 (6.5)	83.2 (8.0)	182.244	0.000[a]	43.2 (4.4)	47.8 (7.8)	51.7 (11.0)	5.340	0.007[a]
PA Mean (SD)	52.6 (9.9)	71.1 (7.8)	87.7 (5.2)	99.486	0.000[a]	51.8 (8.8)	58.0 (7.6)	63.1 (10.7)	7.657	0.001[a]
SC Mean (SD)	60.1 (7.3)	77.7 (7.0)	90.8 (4.1)	119.788	0.000[a]	59.4 (6.9)	64.0 (5.9)	66.8 (6.1)	6.986	0.002[a]
V Mean (SD)	58.1 (6.9)	76.2 (5.3)	94.3 (3.6)	220.805	0.000[a]	57.8 (6.6)	62.7 (6.9)	65.3 (8.0)	5.632	0.006[a]

FP = Foot Pain; FF = Foot Function; FW = Foot Wear; GFH = General Foot Health; GH = General Health; PA = Physical Activity; SC = Social Capacity; V = Vigor.
[a] Statistically significant ($p < 0.05$).

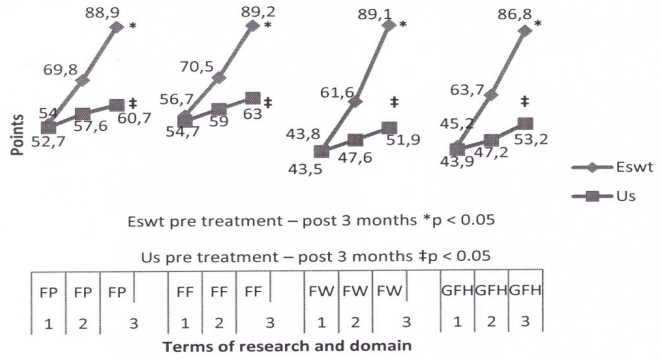


Chart 1 – The scores of Foot Pain (FP), Foot Function (FF), Foot Wear (FW) and General Foot Health (GFH): 1) pre treatment, 2) post treatment, 3) after 3 months

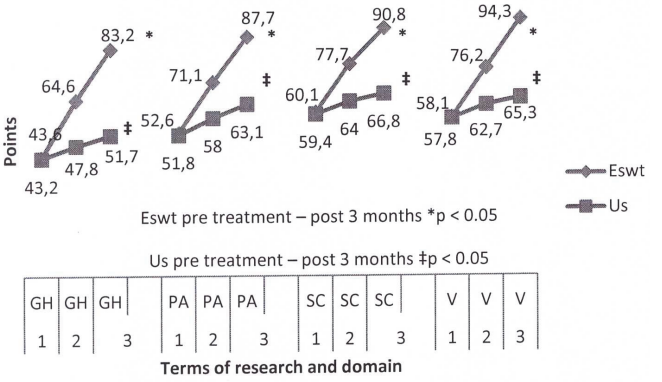


Chart 2 – The scores of General Health (GH), Physical Activity (PA), Social Capacity (SC) and Vigor (V): 1) pre treatment, 2) post treatment, 3) after 3 months

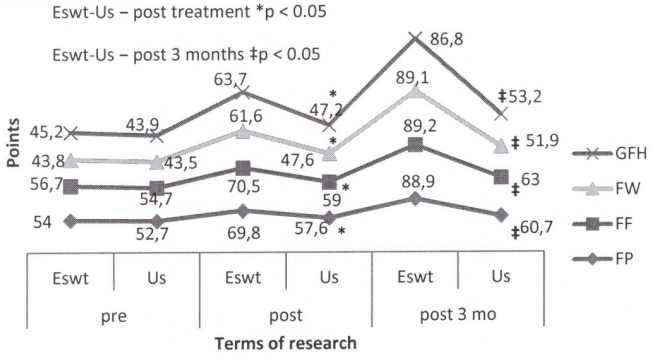


Chart 3 – The scores of Foot Pain (FP), Foot Function (FF), Foot Wear (FW) and General Foot Health (GFH): 1) pre treatment, 2) post treatment, 3) after 3 months

Our results show that the cure that is used improves the patients' quality of life (QOL), and so in the mental as in the physical spheres, reduces the social limitations caused by CS.

Discussion

Although CS is not life threatening, it is a serious orthopedic problem. Uncured CS leads to social limitations, patients withdrawal from professional life, restriction of social contacts, causes job absences and reduction of labor productivity, finally it can also become the reason for someone taking a disability pension. The CS cure increases the state budget costs for healthcare [1, 2]. Those cases

Table 3 – Differences between groups in the following terms of research

Domain	Pre treatment		Post treatment		Post 3 months	
	ESWT group vs. US group	*p*	ESWT group vs. US group	*p*	ESWT group vs. US group	*p*
FP MD (95% CI)	1.3 (–5.8; 8.3)	0.996	12.2 (5.1; 19.3)	0.000[a]	27.1 (20.0; 34.2)	0.000[a]
FF MD (95% CI)	2.0 (–4.6; 8.6)	0.952	11.5 (4.8; 18.1)	0.000[a]	26.2 (19.6; 32.9)	0.000[a]
FW MD (95% CI)	0.3 (–5.8; 6.3)	1.000	14.0 (7.9; 20.1)	0.000[a]	37.1 (31.0; 43.2)	0.000[a]
GFH MD (95% CI)	1.3 (–4.9; 7.5)	0.991	16.5 (10.3; 22.8)	0.000[a]	33.5 (27.3; 39.8)	0.000[a]
GH MD (95% CI)	0.4 (–6.4; 7.2)	1.000	16.7 (9.9; 23.5)	0.000[a]	31.5 (24.7; 38.3)	0.000[a]
PA MD (95% CI)	0.7 (–7.0; 8.5)	1.000	13.0 (5.2; 20.8)	0.000[a]	24.6 (16.8; 32.4)	0.000[a]
SC MD (95% CI)	0.5 (–5.4; 6.3)	1.000	13.7 (7.9; 19.5)	0.000[a]	24.0 (18.2; 29.8)	0.000[a]
V MD (95% CI)	0.3 (–5.5; 6.1)	1.000	13.5 (7.7; 19.4)	0.000[a]	29.0 (23.2; 34.9)	0.000[a]

MD (95% CI) = Mean Difference (95% Confidence Interval); FP = Foot Pain; FF = Foot Function; FW = Foot Wear; GFH = General Foot Health; GH = General Health; PA = Physical Activity; SC = Social Capacity; V = Vigor.
[a] Statistically significant ($p < 0.05$)

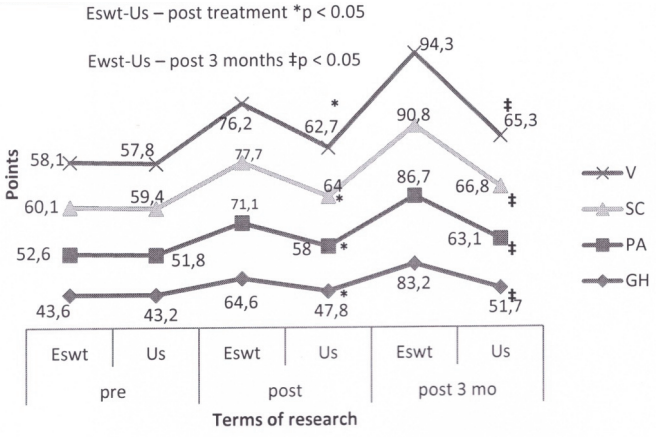


Chart 4 – The scores of General Health (GH), Physical Activity (PA), Social Capacity (SC) and Vigor (V): 1) pre treatment, 2) post treatment, 3) after 3 months

which are resistant to any conservative treatment are qualified for surgery. In general, patients who have foot pain seek doctors and pain relief medication [22–24].

FHSQ is an instrument to assess disease-related foot-health, and may help health professionals in measuring the impact on feet related to CS. FHSQ enables clinicians to compare results and outcomes of their treatments among different populations with different profiles and lifestyles [25]. Therefore, in this study we used FHSQ to compare the effectiveness of ESWT with those of US in prevention of social limitations and the improvement of FHS in men with chronic CS.

The research of Cutts et al. [1] and McMillan at al. [2] shows that CS is a social problem. The results of this study suggest positive outcomes of FHS within groups post treatment, and 3 months after treatment, relative to the baseline scores in men. Although significantly greater effects were achieved in the ESWT group than in the US group. The comparison between the groups showed that ESWT more significantly improved the FHS in all domains than US. Furthermore, the fact that the therapeutic effect persisted for 3 months post treatment, indicates the effectiveness of the ESWT treatment protocol.

The achieved therapy effects show that conservative treatment improves the patients' QOL and FHS. The improvement of such domains as: GH; PA; SC; V points out that the adopted treatment protocol reduces social problems, state budget healthcare costs, and narrows surgery treatment to the typical pathological states. Each surgery intervention is a serious load for patients and is very often the cause of changes in their life style, and even a disability pension.

ESWT has several advantages and should be considered an effective and safe tool in the treatment of chronic CS. As an alternative to surgery it is a noninvasive technology, which has considerably less complications. Finally, ESWT can help in reducing patient suffering, loss of time at work, and health care costs associated with prolonged treatments and surgery.

This study and its results undoubtedly enrich and create knowledge in the branch of theory and practice of physiotherapy in orthopedics. The results give the basis for effective social limitation prevention caused by CS in people of a productive age and later in the geriatric ones.

The study has strengths and limitations. The major strength is the experimental design. The participants and researchers responsible for analyzing the data were unaware of the type of treatment procedure. Another strength is the contribution of two institutions that have the same scientific approach; this fact limits any bias in the

inclusion and assessment of the patients, and also controls the reliability of the method for the therapists working in these two institutions.

The major limitation is the short follow-up period. We do not know about the long-term health benefits of ESWT or US for men suffering from CS. The second limitation is the small sample size, which makes it impossible to establish final conclusions. Our findings are therefore to be read as preliminary ones, in view of possible future long-term studies with a larger sample size to confirm these results and assess the impact of ESWT and US for pain in people suffering from CS.

Conclusion

These findings may be valuable for physicians, physiotherapists, and patients with CS in terms of the selection of the most appropriate treatment on the basis of patients' preference and convenience. In summary, the results of this study provide evidence that patients with CS can obtain significant health benefits to foot care with ESWT.

Conflict of interest

The authors have no conflict of interest to disclose.

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